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EXAMINER

RAMANA, ANURADHA

ART UNIT PAPER NUMBER

3732

DATE MAILED: 10/29/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/779,754

Applicant(s)

STAHMANN ET AL.

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in–

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 48, 49, 63 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Verboven-Nelissen (US 5,720,768).

Regarding claims 48, 49, 63 and 66, Verboven-Nelissen discloses an apparatus and method for pacing and sensing different chambers of a heart wherein a first electrode 159 is placed in the left ventricle, a second electrode 156 is placed in the right ventricle and a pacing and sensing vector is programmed between the two electrodes by an implantable pulse generator 10 (col. 3, lines 12-27, col. 5, lines 23-32 and Figure 5A).

The method steps of claims 48, 49, 63 and 66 are inherently performed during normal use of the Verboven-Nelissen apparatus for the purpose of pacing a heart.

Claims 69-70 are rejected under 35 U.S.C. 102(e) as being anticipated by Schloss (US 6,539,260).

Regarding claims 69 and 70, Schloss discloses an implantable medical device with an implantable ventricular lead 30 having a cathodic first electrode 32 in the right ventricular apex, a second ring electrode or anodic second electrode 34 in the right ventricle at a location more proximal than the first electrode 32 and a defibrillation electrode 36 for delivering stimulation in the form of pacing and shock therapy (Figure 1, col. 1, lines 7-11 and lines 63-67, col. 2, lines 13-22, col. 3, lines 1-27 and col. 4, lines 24-35).

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The method steps of claims 69-70 are inherently performed during normal use of the Schloss device for the purpose of pacing and sensing in a heart.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helland (US 5,431,681).

Helland teaches bipolar pacing between tip electrode 28 acting as a cathode and a defibrillation electrode 30 acting as an anode (col. 6, lines 9-14).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the defibrillation electrode the cathode and the tip electrode the anode, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Regarding claim 56, it is well known to perform unipolar pacing between a tip electrode placed in the apex of a ventricle and a defibrillation electrode spaced from the tip electrode (see cited art).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed pacing between a defibrillation electrode in a ventricle and a tip electrode placed in the apex of a ventricle since it was known in the art to perform unipolar pacing between a tip electrode placed in the apex of a ventricle and a defibrillation electrode spaced from the tip electrode.

Claims 50 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verboven-Nelissen.

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Regarding claims 50 and 67, Verboven-Nelissen discloses that sensing and pacing could occur between a first left ventricular electrode 159 and a conductive housing 134 of implantable generator 10 (col. 5, lines 23-59).

Verboven-Nelissen does not disclose switching from bipolar pacing (first pacing pulse between a left ventricular electrode and a right ventricular electrode) to unipolar pacing (second pacing pulse between a left ventricular electrode and the conductive housing of the implantable generator).

Switching from bipolar pacing to unipolar pacing and vice versa is well known (see cited art).

Accordingly it would have been obvious to one of ordinary skill in the art to have provided a first pacing pulse between a left ventricular electrode and a right ventricular electrode and a second pacing pulse between the a left ventricular electrode and the conductive housing of the Verboven-Nelissen apparatus, to switch from a bipolar pacing mode to a unipolar pacing mode.

Claims 51-54, 64-65 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verboven-Nelissen in view of Schloss.

Regarding claims 51-53, delivering first, second or more pacing pulses to spaced apart sites in a heart is well known in the art (see cited art).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have delivered first and second pacing pulses to first and second spaced apart sites since it was known in the art to deliver first and second pacing pulses to two spaced apart sites in a heart.

Further, regarding claims 52-54, 64, 65 and 68, although Verboven-Nelissen does not disclose first left, second left and third left ventricular electrodes, Schloss teaches a large surface electrode to achieve capture (col. 8, lines 40-49). It is well known to connect multiple electrodes in common to form a large surface electrode (see cited art).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided first left, second left and third left ventricular electrodes in the Verboven-Nelissen device, wherein the first left and second left ventricular electrodes are

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connected in common, or the first left and third left ventricular electrodes are connected in common, or the right atrial electrode is connected to the housing of the implantable housing, as taught by Schloss, to provide a large surface electrode to achieve capture.

Regarding claim 68, Verboven-Nelissen discloses that pacing and sensing can be performed between left ventricular electrode 159 and conductive housing 134 of implantable generator 10 (see discussion for claim 67).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a third left ventricular electrode in the Verboven-Nelissen device connected in common to the first left ventricular electrode 159 to provide a large surface electrode, as taught by Schloss, to achieve capture.

The method steps of claims 51-54, 64-65 and 68 are rendered obvious by the above discussion.

Claims 41, 42, 47 and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schloss.

Schloss discloses an implantable medical device with an implantable ventricular lead 30 having a first electrode 32 in the right ventricular apex and an electrode 22 in the right atrial region wherein pacing and sensing are performed between the right ventricular electrode and the right atrial electrode (Figure 1 and col. 4, lines 17-35).

Although Schloss does not disclose a left ventricular electrode, Schloss discloses that additional stimulation leads with one or more pacing/sensing electrodes may be used in order to efficiently and effectively provide pacing stimulation to the left side of the heart.

Applicant does not disclose the criticality of pacing between an electrode in the right atrium and an electrode in the left ventricle.

Accordingly performing pacing between an electrode in the right atrium and an electrode in the left ventricle is deemed to be a design consideration and does not patentably distinguish over Schloss.

Regarding claims 47 and 58-60, Schloss teaches a large surface electrode to achieve capture (col. 8, lines 40-49). Further, it is well known to connect multiple electrodes in common to form a large surface electrode (see cited art).

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Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided first and third left ventricular electrodes connected in common, to provide a large surface electrode to achieve capture.

The method steps of claims 41, 42, 47 and 57-60 are rendered obvious by the above discussion.

Claims 43-46, 61-62 and 71-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schloss in view of Verboven-Nelissen. See discussion for claims 41 and 57.

Regarding claims 43-46, 61-62 and 71-75, delivering first, second or more pacing pulses to spaced apart sites in a heart is well known in the art (see cited art).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have delivered first and second pacing pulses to first and second spaced apart sites since it was known in the art to deliver first and second pacing pulses to two spaced apart sites in a heart.

Regarding claim 43, Verboven-Nelissen discloses that pacing and sensing can be performed between left ventricular electrode 159 and conductive housing 134 of implantable generator 10.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a first pacing pulse between a first left ventricular electrode and a first atrial electrode and a second pacing pulse between the first left ventricular electrode and a conductive housing of the implantable generator 10, as taught by Verboven-Nelissen to perform multi-site pacing.

Regarding claims 45, 46, 62, 73 and 75, Schloss teaches a large surface electrode to achieve capture (col. 8, lines 40-49). Further, it is well known to connect multiple electrodes in common to form a large surface electrode (see cited art).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided first and second left ventricular electrodes connected in common, or a first left ventricular electrode and a third left ventricular electrode in common, or a

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right ventricular electrode and the housing of an implantable generator in common, to provide large surface electrodes to achieve capture.

Response to Arguments

Applicant's arguments with respect to claims 41-50, 54-60 and 63-70 in Paper No. 12 have been considered but are moot in view of the new ground(s) of rejection.

The indicated allowability of claims 51-53 and 61-62 is withdrawn in view of the newly discovered art. The Examiner apologizes for any inconvenience caused to the Applicants by this withdrawal.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicants' attention is specifically directed to the following patent:

Ayers et al. (US 5,405,375): col. 3, lines 38-54.

Morgan (US 6,094,596): col. 1, lines 29-36.

Ripart et al. (US 6,493,582): col. 1, lines 19-25.

Barreras et al. (US 4,558,702): col. 1, lines 59-64.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR *Anuadella Ramana*
October 24, 2003

Kevin Shaver
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10/27/03